IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 1:20-cv-01029-RGA
	)	
MSN LABORATORIES PRIVATE LTD. and MSN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

FIRST AMENDED COMPLAINT

Plaintiff ACADIA Pharmaceuticals Inc. ("ACADIA" or "Plaintiff"), for its Complaint against Defendants MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals, Inc. ("MSN Pharma") (collectively, "MSN" or "Defendants"), hereby alleges as follows:

THE PARTIES

1. ACADIA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 12830 El Camino Real, Suite 400, San Diego, California 92130.

2. Upon information and belief, MSN Labs is an entity organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad, Telangana, 500018 India.

3. Upon information and belief, MSN Pharma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

4. Upon information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs.

5. Upon information and belief, MSN Pharma acts at the direction, and for the benefit, of MSN Labs and is controlled and/or dominated by MSN Labs.

6. Upon information and belief, MSN Labs and MSN Pharma work in concert, either directly or indirectly, with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in the State of Delaware.

7. Upon information and belief, MSN Labs and MSN Pharma have participated and collaborated in the preparation, filing, and seeking FDA approval of Abbreviated New Drug Application ("ANDA") No. 214925 for pimavanserin tartrate oral capsule, EQ 34 mg base ("the MSN Generic Product"); continue to participate and collaborate in seeking FDA approval of ANDA No. 214925; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and/or sale of the MSN Generic Product throughout the United States including in the State of Delaware.

NATURE OF THE ACTION

8. This is a civil action for infringement of United States Patent Nos. 7,732,615 ("the '615 patent"), 10,646,480 ("the '480 patent"), and 7,601,740 ("the '740 patent") (collectively "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

JURISDICTION & VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 2201, 2202, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

10. Upon information and belief, MSN Pharma is a Delaware corporation and has a registered agent in the State of Delaware, United States Corporation Agents, Inc., located at 221 North Broad Street, Suite 3A, Middletown, Delaware 19709.

11. Venue is proper in this Court as to MSN Pharma under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because MSN Pharma is incorporated in Delaware and thus resides in this Judicial District. MSN Pharma has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

12. This Court has personal jurisdiction over MSN Pharma, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, MSN Pharma is a Delaware corporation and thus resides in Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. Upon information and belief, MSN Pharma intends to engage in the commercial manufacture, use, or sale of the MSN Generic Product under ANDA No. 214925 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

13. Upon information and belief, MSN Pharma has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

14. This Court also has personal jurisdiction over MSN Pharma, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, MSN Pharma

maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates.

15. Venue is proper in this Court as to MSN Labs under 28 U.S.C. §§ 1391(b), (c), (d), and/or 1400(b) because, *inter alia*, MSN Labs, directly or indirectly through its subsidiaries, agents, and/or alter egos, has a regular and established place of business in the State of Delaware, including, at least, MSN Pharma, a wholly owned subsidiary incorporated in the State of Delaware, and has also committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

16. This Court has personal jurisdiction over MSN Labs, and venue is proper in this Judicial District, by virtue of the facts that, *inter alia*, MSN Labs wholly owns a subsidiary that is incorporated in the State of Delaware and has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led to and/or will lead to foreseeable harm and injury to ACADIA, a Delaware corporation, including in the State of Delaware. MSN Labs has indicated that it intends, directly or indirectly through its subsidiaries, agents, and/or alter egos, to engage in the commercial manufacture, use, or sale of the MSN Generic Product under ANDA No. 214925 before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

17. Upon information and belief, MSN Labs has purposely availed itself of the privilege of doing business in Delaware, including by, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of

Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, MSN Pharma.

18. MSN's website states that "MSN Group is the fastest growing research-based pharmaceutical company based out of India" with "more than 40,000,000 customers across 65 countries globally" and has "nine API and five finished dosage facilities established across Hyderabad, USA and Myanmar." Who We Are, http://www.msnlabs.com/who-we-are.html (last visited July 23, 2010). MSN's website also states that its "reach is now global – not just in markets, but [they] also have offices in New Jersey – USA . . . and a few other international locations." Leader in Drug Development, http://www.msnlabs.com/r-and-d.html (last visited July 23, 2020).

19. This Court also has personal jurisdiction over MSN Labs, and venue is proper in this Judicial District, by virtue of the fact that, upon information and belief, MSN Labs maintains pervasive, continuous, and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of Delaware, through its own actions and through the actions of its agents and affiliates, including, at least, MSN Pharma. Upon information and belief, MSN Labs derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in the State of Delaware.

20. MSN's infringing actions with respect to the filing of ANDA No. 214925 and intent to commercialize the MSN Generic Product have led and/or will lead to foreseeable harm and injury to ACADIA.

21. This Court also has personal jurisdiction over MSN Labs and MSN Pharma, and venue is proper in this Court because, *inter alia*, they have previously been sued together in this Judicial District and have not challenged personal jurisdiction or venue, and have purposefully availed themselves of the rights and benefits of the jurisdiction of this Court by filing

counterclaims in this Judicial District. *See*, *e.g.*, *Vanda Pharm. Inc. v. MSN Pharm. Inc.*, C.A. No. 20-0318-CFC (D. Del.) (MSN Labs and MSN Pharma did not contest jurisdiction and filed counterclaims); *Vanda Pharm. Inc. v. MSN Pharm. Inc.*, C.A. No. 20-0235-CFC (D. Del.) (same); *Vanda Pharm. Inc. v. MSN Pharm. Inc.* C.A. No. 19-926-CFC (D. Del.) (same); *Genentech, Inc. v. MSN Labs. Private Ltd.*, C.A. No. 19-0205-RGA (D. Del.) (same); *Boehringer Ingelheim Pharm. Inc. v. MSN Labs. Private Ltd.*, C.A. No. 18-1785-CFC-SRF (D. Del.) (same); *Biogen Int'l GmbH v. MSN Labs Private Ltd.*, C.A. No-18-0337-MN (D. Del.) (same).

22. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over MSN Labs in this action, this Court may exercise jurisdiction over MSN Labs pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) ACADIA's claims arise under federal law; (b) MSN Labs is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) MSN Labs has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical ingredients that are used in the products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

ACADIA'S NDA AND THE PATENTS-IN-SUIT

23. ACADIA holds New Drug Application ("NDA") No. 210793 for oral capsules containing pimavanserin tartrate, Eq. 34 mg base as the active ingredient. ACADIA exclusively manufactures, markets, and sells these oral capsules in the United States under the brand name NUPLAZID®.

24. On June 8, 2010, the '615 patent, entitled "N-(4-fluorobenzyl)-N-(1-methylpiperidin-4-yl)-N′-(4-(2-methylpropyloxy)phenylmethyl)carbamide and its tartrate salt and crystalline forms" was duly and legally issued. A copy of the '615 patent is attached as Exhibit A.

25. ACADIA owns the '615 patent.

26. On May 12, 2020, the '480 patent, entitled "Formulations of pimavanserin" was duly and legally issued. A copy of the '480 patent is attached as Exhibit B.

27. ACADIA owns the '480 patent.

28. On October 13, 2009, the '740 patent, entitled "Selective serotonin 2A/2C receptor inverse agonist as therapeutics for neurodegenerative diseases" was duly and legally issued. A copy of the '740 patent is attached as Exhibit C.

29. ACADIA owns the '740 patent.

30. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUPLAZID® or its use.

MSN'S ANDA AND PARAGRAPH IV NOTIFICATION

31. Upon information and belief, MSN submitted ANDA No. 214925 to the FDA under 21 U.S.C. § 355(j). Upon information and belief, MSN's ANDA No. 214925 seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the MSN Generic Product prior to the expiration of the patents-in-suit.

32. Upon information and belief, by filing ANDA No. 214925, MSN has certified to the FDA that the MSN Generic Product has the same active ingredient as NUPLAZID® and the same or substantially the same proposed labeling as NUPLAZID®.

33. ACADIA received written notifications of MSN's ANDA No. 214925 and its accompanying § 505(j)(2)(A)(vii)(IV) certification by three letters, one dated June 15, 2020 ("MSN's 6/15 Notice Letter"), one dated June 18, 2020 ("MSN's 6/18 Notice Letter"), and one dated October 12, 2020 ("MSN's 10/12 Notice Letter") (collectively, "MSN's Notice Letters").

34. MSN's Notice Letters represent that MSN certified in ANDA No. 214925 that the claims of the patents-in-suit are invalid or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the MSN Generic Product.

35. According to applicable regulations, Notice Letters such as MSN's Notice Letters must contain a detailed statement of the factual and legal bases for the applicant's opinion that the patent is invalid, unenforceable, or not infringed, which includes a claim-by-claim analysis, describing "[f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 C.F.R. § 314.95(c)(7); *see also* 21 C.F.R. § 314.52.

36. This action is being commenced by ACADIA within 45 days of its receipt of MSN's Notice Letters.

COUNT I – INFRINGEMENT
BY MSN LABS AND MSN PHARMA

37. ACADIA re-alleges paragraphs 1-36 as if fully set forth herein.

38. MSN's submission of ANDA No. 214925 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), MSN certified in ANDA No. 214925 that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use, sale, or offer for sale of the MSN Generic Product. MSN notified ACADIA of that certification and provided a statement of the alleged bases for its claims.

40. MSN's 6/15 Notice Letter represented that ANDA No. 214925 included a § 505(j)(2)(A)(vii)(IV) certification with respect to the '615 patent.

41. MSN's 6/18 Notice Letter represented that ANDA No. 214925 included a § 505(j)(2)(A)(vii)(IV) certification with respect to the '480 patent.

42. MSN's 10/12 Notice Letter represented that ANDA No. 214925 included a § 505(j)(2)(A)(vii)(IV) certification with respect to the '740 patent.

43. MSN's Notice Letters do not identify any factual basis for, or any opinion of, invalidity regarding the claims of the '615 and '480 patents.

44. MSN's Notice Letters do not identify any factual basis for, or any opinion of, noninfringement regarding claims 1 and 9-26 of the '740 patent.

45. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214925 seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the MSN Generic Product prior to the expiration of the patents-in-suit.

46. Upon information and belief, MSN was aware of the existence of the patents-in-suit and were aware that the filing of ANDA No. 214925 and certification with respect to the patents-in-suit constituted an act of infringement of those patents.

47. MSN filed ANDA No. 214925 without adequate justification for asserting that the patents-in-suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the MSN Generic Product.

48. Moreover, if MSN manufactures, uses, offers for sale, or imports into the United States any of the MSN Generic Product, or induces or contributes to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, it would infringe one or more claims of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

49. ACADIA is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of MSN's ANDA No. 214925 be a date that is not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity for the patents-in-suit to which ACADIA is or becomes entitled.

50. ACADIA will be irreparably harmed by MSN's infringing activities unless those activities are enjoined by this Court. ACADIA does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, ACADIA requests that the Court grant the following relief:

A. A Judgment that MSN has infringed the '615, '480 and '740 patents by submitting ANDA No. 214925 to the FDA;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of MSN's ANDA No. 214925 will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which ACADIA is or becomes entitled;

C. An Order permanently enjoining MSN, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with MSN, from commercially manufacturing, using, offering to sell, selling, marketing, distributing, or importing the MSN Generic Product identified in this Complaint, or any product that infringes or induces or contributes to the infringement of one or more of the patents-in-suit, prior to the

expiration of the patents-in-suit, including any exclusivities or extensions to which ACADIA is or becomes entitled;

D. That ACADIA be awarded monetary relief to the extent MSN commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extensions or exclusivities for the patents-in-suit to which ACADIA is or will become entitled, and that any such monetary relief be awarded to ACADIA with prejudgment interest;

E. A finding that this case is an exceptional case and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. That ACADIA be awarded the costs and expenses that it incurs in prosecuting this action; and

G. Such other and further relief as this Court may deem just and proper.

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